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Core Material of Catheter Guide Wire and Catheter Guide Wire
[Kateiteru Gaido Waiyaa-no Shinzai oyobi Kateiteru Gaido Waiyaa]

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Specification

/369*

1.Title of the Invention

Core Material of Catheter Guide Wire and Catheter Guide Wire

2. Claim

(1) A core material for a catheter guide wire characterized as a catheter guide wire core material having a front end part and a base part configured so that they form a single piece and at least the abovementioned base part is made up of a TiNi group shape-memorizing alloy containing C.

(2) A core material for a catheter guide wire as described in Claim 1, the invention characterized as follows. The abovementioned TiNi group shape-memorizing alloy has a composition made up of Ni in an amount wherein the intermediate phase manifests by aging processing of 0.25 to 5.0 at % C and at 600 °C and under with the balance essentially made up of Ti, having elastic properties at a temperature of at least body temperature (≈ 37 °C).

(3) A core material for a catheter guide wire as described in Claim 1, wherein twist transmission characteristics are provided the abovementioned base part and pliability is provided the abovementioned front end part by 1 to 30 minutes of heat treatment of the part making up the base part at a temperature of less than 400 °C and by heat treatment of the part making up the front end part for 1 to 120 minutes at a temperature of 400 to 550 °C for the TiNi group

* Numbers in the margin indicate pagination in the foreign text.

shape-memorizing alloy wire containing the abovementioned C which has been processed and hardened.

(4) A catheter guide wire characterized as follows. A synthetic resin is coated on the core material of the catheter guide wire in any of Claims (1) through (3).

3. Detailed Description of Invention

(Industrial Use)

The present invention relates to a core material for a catheter guide wire, which is a medical device, and a catheter guide wire.

(Prior Art)

Catheter guide wires are medical devices which are introduced to blood vessels using a Seldinger needle which has punctured the blood /370 vessels; then, the Seldinger needle is removed from the guide wire, the guide wire is introduced to the catheter as far as the blood vessel of the subject, particularly as far as the desired site inside the blood vessel, thereby guiding the catheter.

As a result, the core material of the catheter guide wire is made up of a front end part having a complex shape and a base part having a linear shape. Moreover, the core material must have reversible energy absorption and discharge properties as well as elastic properties enabling reversible shape deformation and restoration accompanying application and removal of deformation stress, including twisting occurring during introduction to the blood vessels, as well as moving at body temperature (≈ 37 °C).

Conventional coiled stainless steel wire or piano wire or monofilament shaped plastic is used as a core material which retains these properties. Moreover, recently, the superelastic functions of TiNi alloys are increasingly coming into wider use (see JP-A (Tokkai) S60-63066).

Alloys made up of TiNi and TiNiX (X = Fe, Cu, Cr, V,...) are known to have a pronounced shape-memorizing effect incidental to reverse transformation of thermo-elastic type martensitic transformation. Moreover, it is known to combine superelasticity which exhibits the same type of behavior of rubber based on the same principle.

Moreover, the inventors found that even if a TiNi alloy had C added to it, the essential TiNi alloy properties are not damaged and it is useful in improving the shape-memorizing properties, particularly the reversible shape-memorizing effect. (Tohoku University Selected Research Reports June 1981, Vol. 38 and JP-A (Tokkai) S63-11636).

[Problems Which the Present Invention is Intended to Solve]

However, a TiNi alloy used for the core material of a guide wire had pliability with outstanding restorative properties whereas it was lacking in rigidity when compared to conventional stainless steel wire and the like. As a result, it was sometimes difficult to introduce the guide wire to the desired site inside the body due to inevitable resistance and restrictions of use.

Therefore, the technical problem in the present invention provides the same type of elasticity as the conventional TiNi alloy on the front end part at a temperature of at least body temperature (≈ 37 °C) as well as sufficient rigidity on the base part.

[Means Used to Solve the Problems]

The present invention provides a core material for a catheter guide wire characterized as having a front end part and a base part configured so that they form an integrated part and being made up of a TiNi group shape-memorizing alloy wherein at least the abovementioned base part contains C.

Moreover, the present invention is characteristic in that the abovementioned TiNi group shape-memorizing alloy contains 0.25 to 5.0 at % of a C constituent and having a composition made up of Ni in an amount such that the intermediate phase appears due to an aging effect of not more than 600 °C and the balance made up essentially of Ti and having elastic properties at a temperature of at least body temperature (=37 °C).

Moreover, the present invention is a core material for a catheter guide wire characterized as follows. It is a TiNi group shape-memorizing alloy wire containing C which has been processed and hardened; the part making up the base part is subjected to a heat treatment of 1 to 30 minutes at a temperature of less than 400 °C and the part making up the front end part is subjected to heat treatment of 1 to 120 minutes at a temperature of 400 °C to 550 °C so that

twist transmission characteristics can be provided the base part and pliability can be provided the front end part.

The present invention is a catheter guide wire characterized as covering the TiNi group shape-memorizing core material containing the abovementioned C using a synthetic resin.

It is generally known that when C is added to a TiNi alloy, it generally reacts with the C in matrix φ and mainly generates TiC and lowers the transformation temperature of the alloy. However, the present invention is characteristic in that simply adding C not only lowers the transformation temperature of the alloy but it is thought that TiC, which has been fiberized by processing, is related to an improvement in mechanical properties. Moreover, it is thought that the intermediate phase appears due to an aging temperature of not more than 600 °C to obtain superelasticity at a temperature of at least 37 °C using the TiNi alloy. When this depends on the aging, after solution treatment is carried out, the Ni concentration must be at least 50.0 at %. Moreover, when this is carried out by the same type of aging after processing hardening, the Ni concentration /371 should be 49.0 at % and above. When aging processing is carried out which easily provides relatively good superelasticity at approximately 500 °C, the Ni must be at least 50.2 at %. The same type of conditions are required at least for the TiNi alloy, even for the TiNi group alloy with C added used in the present invention. However, as long as the total amount of Ni + C is at least 50.0 at %,

a good superelasticity can be obtained by the transformation temperature lowering effect brought about by adding the C. The amount of C added which was required to bring out these effects should be 0.5 to 5.0 at %. Therefore, when this is less than 0.5 at %, the addition effect is slight. When it exceeds 5.0 at %, problems with the processing increase. Further, when the aging temperature for the base part is less than 400 °C and the aging time for the base part ranges from 1 to 30 minutes and the aging temperature increases, the rigidity tends to decline and does not satisfy the purpose of the present invention. The aging time by no means needs to be fixed for 1 to 30 minutes. If the temperature is 200 °C, the aging time is 100 minutes and if the temperature is 600 °C, the aging time may even be 0.5 minutes. For practical purposes, the abovementioned aging time is appropriate. Moreover, this is a practical range for the pliability of the front end part and it need not satisfy these conditions. Therefore, pliability may be obtained at 200 hours at 350 °C or approximately 2 minutes at 600 °C.

[Practical Example]

Next, we shall explain a practical example of the present invention referring to figures.

The TiNi group alloy obtained using the dissolving method is processed by hot and cold rolling processing up to 0.7 min. After we made a solution of this at 950 °C x 10 minutes (the same follows hereinafter), we cold rolled it up to a diameter of 0.50 mm. After we

carried out heat treatment of part of the wire material obtained for 5 minutes at 300 °C and 30 minutes x 500 °C, we measured the elastic properties at 37 °C using the tensile test at 3 % traction.

Figure 1 is a graph indicating the relation between the value for the stress at elongation of 2 % for the TiNi group alloy expressed by the formula $Ti_{50-x/2}Ni_{50-x/2}C_x$ $Ti_{49-x/2}Ni_{51-x/2}C_x$ (x=0,1,2,3) and the amount of C added. In the figure, curve (1) is the stress value for the annealed material for the $Ti_{50-x/2}Ni_{50-x/2}C_x$ at 300 °C at 5 minutes; curve (2) is the stress value for the annealed material for the same at 500 °C at 30 minutes. Curve (3) is the stress value for the annealed material for $Ti_{49}Ni_{51-x}C$ at 300 °C at 5 minutes. Curve (4) is the stress value for the annealed material for the same at 500 °C for 30 minutes. However, in all of these groups, the stress value accompanying the amount of C added tends to increase. A conspicuous effect is seen particularly in low-temperature aging processing curves (1) and (3) at 300 °C at 5 minutes.

Because of this, it was found that when C is added to the TiNi alloy, a great deal of stress is applied. In other words, the feeling of rigidity can be improved by low-temperature aging and rigidity equal to or greater than the conventional rigidity can be provided by aging at approximately 500 °C. Moreover, Figure 2 indicates the stress strain curve at 37 °C for the sample at 10 minutes, 30 minutes, 100 minutes, and 150 minutes of aging at 500 °C for the $Ti_{49}Ni_{50.5}C_{0.5}$ alloy wire which is one alloy in the practical example of

the present invention. It was found that good superelasticity could be obtained even in an alloy with C added and the pliability for it can be controlled freely by adjusting the aging time.

Moreover, in another method, we used only the base part as the TiNi alloy wire with added C aged at low temperatures. It was found that these could be made an integrated piece by joining and the like using a TiNi group superelastic processing alloy wire on the front end part.

Next, we shall describe a practical example of the guide wire.

The synthetic resin coating 4 has an outer diameter which is virtually uniform and includes the front end part. In particular, this synthetic resin coating 4 has an outer diameter which is virtually uniform. Polyethylene, polyvinyl chloride, polyester, polypropylene, polyamide, polyurethane, polystyrene, fluorine resin, silicon rubber or a variety of elastomers and composite materials and the like are suitable for use as synthetic resin coating 4, as indicated in Figure 3. Then, synthetic resin coating 4 is soft enough so that it does not interfere with the curve in inside core 2. The outer surface should be smooth enough so that there is no unevenness on the surface. Further, silicon rubber, urethane and silicon block copolymers (Abcosan, registered trademark), hydroxyethylene methacrylate-styrene copolymer, and other anti-thrombogenic materials may be used as a coating.

Moreover, the friction characteristics of guide wire 1 may be /372

lowered by forming synthetic resin coating 4 using a resin having a low-friction surface made of fluorine resin and the like and by coating silicone oil and other lubricating coating solution on the outside surface of synthetic resin coating 4. Furthermore, a fine powder substance having X-ray contrast characteristics by using Ba, W, Bi, Pb, and other metal simple substances or compounds in the synthetic resin may be used to form synthetic resin coating 4. The total position confirmation of guide wire 1 while introducing inside the blood vessels by doing this can be carried out easily. Synthetic resin coating 4 has an outside diameter which is virtually uniform, as indicated above. The phrase “virtually the same” does not mean that it is restricted to being completely uniform and indicates that the front end part has a somewhat narrow diameter. Thus, by making the part up to the front end part virtually the same, the front end of the guide wire can reduce damage which may affect the inner wall of the blood vessel.

The outside diameter of the synthetic resin coating should be 0.25 to 1.04 mm and preferably 0.30 to 0.64 mm. The thickness of core material 2 on the entire part 2a should be 0.03 to 0.30 mm and preferably 0.05 to 0.20 mm.

Moreover, synthetic resin coating 4 is covered so that it closely adheres to inner core 2 because of the synthetic resin and it should be fixed even on the front end part of inner core 2 and the base part. Further, synthetic resin coating 4 is formed using a

hollow pipe and may be fixed by bonding or melting and forming with inner core 2 on the front end part of inner core 2 and the base part or a part which is suitable for the inner core. Then, the front end (front end of synthetic resin coating 4) of guide wire 1 prevents damage to the wall of the blood vessel and improves the operating characteristics of guide wire 1 so that it should be a curved surface which is hemispherical and other shapes, as indicated in Figure 3.

Moreover, a substance having lubricating characteristics should be fixed to the surface of synthetic resin coating 4. The phrase "substance having lubricating characteristics" means a substance which has lubricating characteristics during lubrication. Specifically, this indicates a water-soluble polymer substance or a derivative thereof.

Therefore, core material 2 of the guide wire in the practical example of the present invention is made as follows. It has an overall length of 1800 mm. The diameter of the front end is 0.06 mm and the diameter of the rear end is 0.25 mm. The diameter is reduced so that it is tapered 120 mm from the front end towards the rear end.

Further, polyurethane containing 45 wt % of a tungsten fine powder is coated on the outside surface of the entire core material so that the entire outside diameter is virtually uniform. Then, we coated a solution made by dissolving anhydrous ethyl maleate ester copolymers in tetrahydrofuran on the surface of the synthetic resin coating formed using the abovementioned polyurethane so that it was

5.0 wt %, fixed the anhydrous ethyl maleate ester and formed a surface having lubricating characteristics.

The overall length of this guide wire was approximately 1800 mm and the overall diameter was 0.36 mm.

[Effect of Invention]

Te present invention provides a core material for a catheter guide wire which increases the twist transmission characteristics of the base part and which is pliable on the front end part.

4. Brief Explanation of Figures

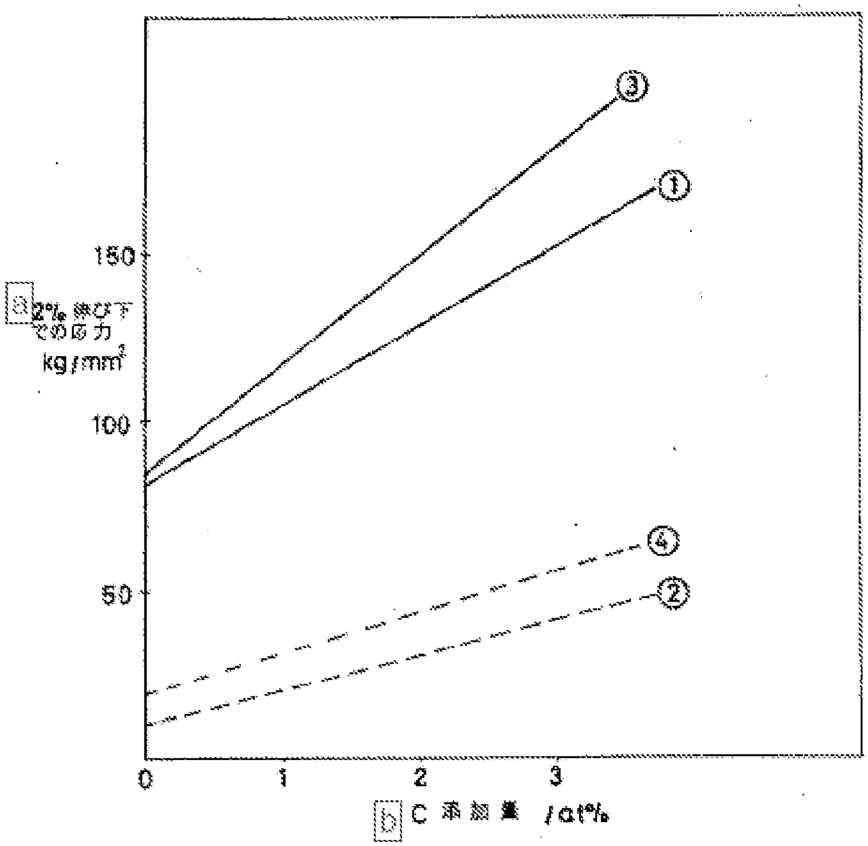
Figure 1 indicates the relation between the amount of C added to the alloy wire and expressed by this format: $Ti_{50-x/2}Pd_{50-x/2}C_x$, $Ti_{49-x/2}$ $Ni_{50-x/2}$ C_x (x = 0 to 3) and the stress.

Figure 2 is a figure indicating the stress-strain curve for a sample processed for 10 minutes, 30 minutes, 100 minutes and 150 minutes at 500 °C of $Ti_{49}Ni_{50.5}C_{0.5}$ alloy wire.

Figure 3 is a lateral view of the catheter guide wire covered with the synthetic resin in the present invention.

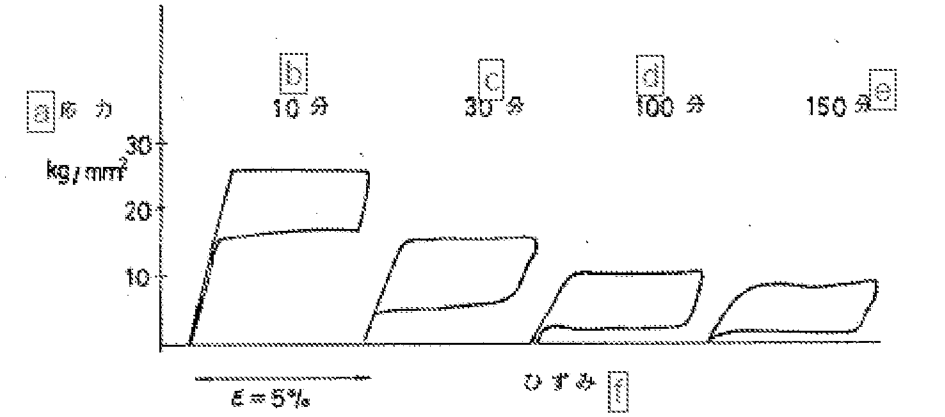
In the figures, 1..guide wire; 2..inner core; 2a..inner core main body part; 4..synthetic resin.

[Figure 1]



Key:
a) stress under 2 % elongation kg/mm^2
b) amount of C added /at %

[Figure 2]



Key:
a) stress
b) 10 minutes
c) 30 minutes
d) 100 minutes
e) 150 minutes
f) stress.

[Figure 3]